

**REMARKS**

Claims 1 and 8 are hereby amended. Claims 2, 3-5, 9 and 12 have been cancelled. Claims 1, 6-8, 10 and 11 are pending in the application.

The invention as claimed covers:

*"A process for drying or concentrating a polyhydroxyalkanoate (PHA) in a polar solvent solution comprising submitting said solution to microwaves for a period of between 30 seconds to 90 minutes to reduce polar solvent concentration from said solution, wherein said process induces between 0% and 25% degradation of said polyxydroxyalkanoate. "*

**Claim Rejections – 35 USC § 103**

Claims 3-12 have been rejected as allegedly being obvious over Ferraris (US 2003/0022883) in view of Tweedy (US 6,175,037). Applicant fails to see the Examiner's connection between these two documents (either alone or in combination) and the present invention and therefore respectfully disagrees with this rejection. Reconsideration by the Examiner is respectfully requested, based on the following arguments.

Several factual inquiries must be made to determine obviousness or non-obviousness of patent application claims under 35 U.S.C. § 103. The basic inquiry was set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966) and includes: (1) determining of the scope and content of the prior art; (2) comparing the differences between the prior art and the claims at issue; and (3) ascertaining the level of ordinary skill in the pertinent art. See also *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1734 (2007). In *KSR*, the Court admonished that it is important to identify reasons to combine the prior art elements in the manner claimed. The *KSR* Court stated that when considering obviousness of a combination of known elements, the operative question is

"whether the improvement is more than the predictable use of prior art elements according to their established functions". *Id.* at 1396. An Examiner bears the initial burden of presenting a *prima facie* case of obviousness. *In re Oetiker*, 977 F.2d 1443, 1445-1446 (Fed. Cir. 1992). Once the Examiner presents a *prima facie* case, the Applicants may present evidence of secondary considerations. Obviousness is then determined on the basis of the evidence as a whole. *Id.*

Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness based upon governing case law including KSR, the examination guidelines for determining obviousness under 35 U.S.C. § 103 (M.P.E.P. Section 2141), and decisions of the Board of Patent Appeals and Interferences applying same. The Examiner provides no reason to combine Ferraris and Tweedy and in addition, the combination of Ferraris and Tweedy does not lead one skilled in the art to all elements claimed.

Broadly, the Ferraris invention refers to a very specific method of making enzyme-inhibiting compounds with possible pharmaceutical applications. It is a process that makes use of classic organic chemistry methods for synthesizing compounds. In no case does Ferraris teach any drying method, much less any method that makes use of microwaves for the purpose of solvent evaporation.

Paragraph 118 mentions that acid addition salts, hydrates, esters or solvates of the basic compounds may be obtained by dissolving the inhibitors in a solvent and then evaporating or concentrating the solvent. First, in no case is any reference made to the method used to evaporate the solvent, except in the examples, where "*in vacuo*" technique is referred to (and not microwaves). Vacuum evaporation is a widespread technique in synthetic organic chemistry and does not involve the use of microwaves.

Paragraph 130 deals with the degree of polarity of the molecules in their tubular diffusion, and, incidentally, with their capacity for retention in the organism. The only connection with our invention would seem to us to be the word "polar". In our case, we are dealing with evaporation of the polar solvent from the solution containing the polymer. In no

case are we dealing with the effect of the polarity of the solvent on the polarity of our polymer (which, moreover, has no effect). The reactions described by Ferraris are metabolic reactions that take place *in vivo* and affect the polarity of the molecules. The present invention deals with an industrial process (not an *in vivo* one!) which has no effect on the polarity of the molecules involved.

Paragraph 399 concerns an example that includes a drying and concentration *in vacuo* phase. Once again, the drying method mentioned therein does not involve the step of submitting the solution to microwaves under such conditions as to avoid or diminish degradation of the polymer.

Paragraph 543 contains a definition of "radiosensitizer", a molecule which, when administered, increases the sensitivity of cells to radiation. The paragraph lists the types of radiation that are used in treating various diseases, which cover a broad portion of the electromagnetic spectrum and include microwaves. This, in our opinion, has no relationship with our invention. In no case does the inventor disclose the use of microwaves for drying; rather, the word forms part of the definition of radiation, which he sees fit to define so that an accompanying context for the use of his molecule is provided and certain side effects of radiation exposure can be avoided.

Tweedy teaches a technique for synthesizing esters. The reaction requires a heating phase to start the components condensing. The heat source claimed are microwaves. In no case is there any question of evaporation, concentration or drying of a polar solvent using microwaves.

In contrast, while the process of the present application involves the drying or concentrating of a biodegradable polymer by removing a solvent, the process disclosed by Tweedy is rather directed towards the condensation of hydroxy groups for the production of acrylate esters in a reaction vessel in the presence of a catalyst under microwave energy as a heating source, the key word here being **heating**. Indeed, Tweedy indicated clearly that the reaction is not intended to remove the solvent from the reaction since it can be solventless (see Abstract):

inhibitor in a reaction vessel, in the presence or absence of a solvent, under microwave energy as a heating source. Advantages of using microwave energy in place of conventional thermal heating include higher temperatures coupled with shorter residence times, reduced production costs, increased capacity, lower energy costs, effective use of raw materials, and solventless processing which is environmentally friendly.

See also column 3, lines 54-57: "*Once generated, the microwaves are transferred to the reactants*". In fact, **Tweedy would lead one skilled in the art away from the present method** of the invention since Tweedy teaches clearly that microwaves produce a change that alters the nature of the original reactants to produce a different reaction product. On the contrary, the present method does not alter the nature of the original polymer (PHA) being submitted to microwave drying and therefore based on the teaching of Tweedy, one skilled in the art would be reluctant to use microwave to dry a PHA solution for fear of altering the nature of the polymer. Indeed, one skilled in the art will recognize that in general, polyesters are degraded under the effect of heat. Therefore, the process as now claimed is surprising inasmuch as it does not cause degradation of polyesters under the effect of microwaves. There is no reasonable expectation of success, which is one of the three basic criteria that must be met to establish a *prima facie* case of obviousness, as stated in MPEP section 706.02(j).

As stated in MPEP section 706.02(j), "*To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references.*" *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). ... "*It is important for an examiner to properly communicate the basis for a rejection so that the issues can be identified early and the applicant can be given fair opportunity to reply. ... it is important that the written record clearly explain the rationale for decisions made during prosecution of the application.*"

The Examiner merely asserts in the Office Action that Ferraris discloses a process for drying a biodegradable polymer comprising submitting to microwaves and that Tweedy discloses the specific parameters of the method. The Examiner summarily concludes that it would have been obvious to utilize the conditions as disclosed by Tweedy to the microwaves as disclosed by Ferraris. The Examiner fails, however, to provide any articulated reasoning with rational underpinning to support the legal conclusion of obviousness as required by *KSR*. See *KSR*, 127 S. Ct. at 1740-41.

A *prima facie* case has not been made because the Examiner's conclusion lacks rational underpinning

When comparing the differences between the prior art and the claimed invention, one must cast his mind back to the time of the invention and resist the temptation to employ hindsight, which may cause one to misinterpret the simplicity of a solution as obvious. See *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000). Therefore, it is important to note that obviousness cannot be established by simply combining the teachings of the prior art to produce the claimed invention. *KSR*, 127 S. Ct. at 1741; *In re Napier*, 55 F.3d 610, 613 (Fed. Cir. 1995). In *KSR*, the Court reaffirmed that "*a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.*" *KSR*, 127 S. Ct. at 1741. Indeed, often it will "*be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine*" previously known elements. *Id.*

A recent case from the Board of Patent Appeals and Interferences (the "Board") exemplifies that the Board rejects, as it must, merely conclusory statements lacking rational underpinning. In *Ex parte Girouard et al.*, Appeal 2007-3307 (BPAI 2008), the Board stated that *KSR* requires an **explicit analysis**, when a conclusion of obviousness is based on **interrelated teachings** of multiple patents, of the effects of demands known to the design community or present in the marketplace and the background knowledge possessed by a person having ordinary skill in the art. *Id.* The Board also stated that the obviousness analysis is not complete until an explanation is provided as to why one having ordinary skill in the art would

have been led to apply a teaching, particularly in light of the contrary teachings pointed out by the applicant(s). The Board found that the Examiner had failed to provide any articulated reasoning with rational underpinning to support a legal conclusion of obviousness.

As the combination of the two references teaching engine supports associated with snowmobile frames is improper (see *Ex parte Girouard et al.*), the combination of two references having diverging objective, one teaching a "*in vacuo*" drying in a conventional manner and the other teaching microwave heating to induce solventless condensation reaction of two reactants, is also improper. It is not sufficient to conclude that microwave drying is equivalent to conventional "*in vacuo*" drying. The obviousness analysis is not complete as the Examiner has failed to provide an explanation as to how one having ordinary skill in the art would have been led to apply the Tweedy teaching of microwave heating to the "*in vacuo*" drying of Ferraris. On the contrary, both documents, when read as a whole, would lead one away from drying with microwaves for fear of inducing reaction causing degradation of the polymer.

As such, the Examiner has therefore failed to establish a *prima facie* case of obviousness and is requested to withdraw the rejection. Should the Examiner persist in his interpretation of the cited prior art, he is respectfully requested to clearly and specifically pinpoint the relevant portions of the documents providing: a) some suggestion or motivation to combine; b) reasonable expectation of success; and c) teaching or suggestion of all claim limitations.

Therefore, it is submitted that all claims as amended are not obvious over the references by Ferraris in view of Tweedy. The rejection must be withdrawn.

In view of the above, examination of claims 1, 6-8, 10 and 11 on their merits and allowance at an early date is earnestly solicited.

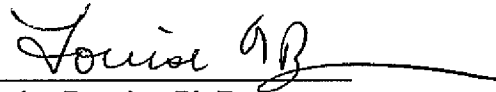
Finally, the Examiner is respectfully informed that the corresponding European application EP 1468102 has now been allowed and will soon mature into a European patent.

A fee of \$555 for a Small Entity is required by this Response as the payment of a three month extension of time for replying. As well, as fee of \$405 for the Request for Continued Examination is hereby provided. The Commissioner is hereby authorized to charge these amounts to deposit account number 19-5113. No further fees are believed to be required by this response. However, should this be an error, authorization is hereby given to charge deposit account number 19-5113 for any underpayment or to credit any overpayment.

In the event that there are any questions concerning this amendment or the application in general, the Examiner is respectfully urged to telephone the undersigned so that prosecution of the application may be expedited.

Respectfully submitted,

**BIOMATERA INC.**

A handwritten signature in cursive script, appearing to read "Louise AB", followed by a horizontal line.

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